

Full Text PA-95-053

MENTORED CLINICAL SCIENTIST DEVELOPMENT AWARD

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National Institute of Allergy and Infectious Diseases

National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Cancer Institute

National Institute of Child Health and Human Development

National Institute on Deafness and Other Communication Disorders

National Institute of Dental Research

National Institute of Diabetes and Digestive and Kidney Diseases

National Institute on Drug Abuse

National Institute of Environmental Health Sciences

National Eye Institute

National Heart, Lung, and Blood Institute

National Institute of Mental Health

National Institute of Neurological Disorders and Stroke

Application Receipt Dates: February 1, June 1, and October 1

PURPOSE

The purpose of the Mentored Clinical Scientist Development Award MCSDA is to support the development of outstanding clinician research scientists. This mechanism provides specialized

study for clinically trained professionals who are committed to a career in research and have the potential to develop into independent investigators. The award supports a three, four, or five year period of supervised research experience that may integrate didactic studies with laboratory or clinically-based research. The proposed research should have both intrinsic research importance and be a suitable vehicle for learning the methodology, theories, and conceptualizations necessary for a well trained independent researcher.

Because of the focus on progression to independence, the prospective candidate should propose a period of study and development consistent with this goal and his or her previous research and clinical experience. For example, a candidate with limited experience in a given field of research may find a phased developmental program lasting for five years which includes a designated period of didactic training and supervised research experience the most efficient means of attaining independence. A candidate with substantial previous research experience may require a shorter award period appropriate for the transition to independence. The entire program should be comparable in scope and rigor to meeting the requirements for an advanced research degree.

This award replaces the Clinical Investigator Award (K08), the Physician Scientist Award (K11), the Dentist Scientist Award (K15), and the Scientist Development Award for Clinicians (K20). Individuals who were eligible to apply for one of these awards are now directed to apply for an MCSDA. Therefore, this program announcement supersedes all previous K08, K11, K15 and K20 program announcements and competing applications for these awards will no longer be accepted. Existing policies and provisions will remain in effect for current K08, K11, K15 and K20 recipients until completion of the non-competing years of their career development program.

The NIH institutes and centers implement this award in different ways to accommodate the career needs of researchers in fields within their missions. For example the National Institute of Dental Research (NIDR) requires that, in most situations, candidates must pursue a program that includes didactic and supervised basic or behavioral science research experiences that result in the Ph.D. degree. The NIDR may, under specific circumstances, provide support under this program for the development of advanced clinical knowledge and skills in either a recognized clinical specialty or equivalent dental clinical discipline. Therefore, the prospective candidate must have a D.D.S. or an equivalent degree but need not have started postgraduate training, such as in a clinical specialty or general practice dental residency. However, preference will be given to applicants with advanced training in general or specialty practice. Dentists without advanced clinical knowledge and skills are eligible for the MCSDA but are encouraged to seek appointments to the Mentored Clinical Scientist Development Program Award (K12). All

applicants are strongly encouraged to contact the prospective awarding component to discuss issues of eligibility and the specific provisions of this award.

The NIH recently reviewed its career awards (K) used to develop the research capabilities of clinicians and other scientists needed to carry out the nation's research mission in the biomedical and behavioral sciences. This evaluation resulted in several changes:

(1) the total number of K mechanisms were reduced from 19 to six; (2) the review criteria were refined to clarify the career development goals of the K award; and (3) K award applications will be assigned to initial review groups managed by the prospective funding institute or center to which the application has been assigned.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Mentored Clinical Scientist Development Award, is related to the priority area of human resource development. Potential candidates may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

The candidate must have a clinical degree or its equivalent, must have initiated postgraduate clinical training, must identify a mentor with extensive research experience, and must be willing to spend a minimum of 75 percent of full-time professional effort conducting research and research career development.

Applications may be submitted, on behalf of candidates, by domestic, non-Federal organizations, public or private, such as medical, dental, or nursing schools or other institutions of higher education. Minorities and women are encouraged to apply. Candidates must be U.S. citizens or noncitizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551) or some other verification of legal admission as a permanent resident. Noncitizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S. They are usually born in lands that are not states but are under U.S. sovereignty, jurisdiction, or administration. Individuals on temporary or student visas are not eligible.

Former principal investigators on NIH research project (R01), FIRST Awards (R29), sub-projects of program project (P01) or center grants (P50), or the equivalent, are not eligible. A candidate for the MCSDA may not concurrently apply for any other PHS award that duplicates the provisions of this award nor have another application pending award. MCSDA recipients are encouraged to apply for independent research grant support during the period of this award.

MECHANISM OF SUPPORT

Awards in response to this program announcement will use the K08 mechanism. Planning, direction, and execution of the program will be the responsibility of the candidate and her/his mentor on behalf of the applicant institution. The project period may be for three, four or five years and will depend upon the number of years of prior research experience, the need for additional experiences to achieve independence, and the policy of each particular institute or center. Awards are not renewable.

RESEARCH OBJECTIVES

A. Environment: The institution must have a well-established research and clinical career development programs and qualified faculty in clinical and basic research to serve as mentors. The institution must be able to demonstrate a commitment to the development of the candidate as a productive, independent investigator. And, the candidate, mentor and institution must be able to describe a multi-disciplinary career development program that will maximize the use of relevant research and educational resources.

B. Program: The award provides three to five consecutive 12 month appointments. At least 75 percent of the recipient's full-time professional effort must be devoted to the program and the remainder devoted to other clinical and teaching pursuits consonant with the objectives of the award. The basic science component must develop knowledge and research skills in scientific areas relevant to the career goals of the candidate.

C. Mentor(s): The recipient must receive appropriate mentoring throughout the three to five year program. Where feasible, women and minority mentors should be involved as role models.

D. Allowable Costs:

1. Salary: The NIH will provide salary and fringe benefits for the K recipient. The salary limits are not uniform throughout the NIH and are determined independently by each component of the NIH. Therefore, prospective candidates should contact the NIH component to which the application is targeted to ascertain the maximum contribution to the candidate's salary.

The institution may supplement the NIH contribution up to a level that is consistent with the institution's salary scale; however, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which such funds are derived. In no case, may PHS funds be used for salary supplementation. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the MCSDA. Under expanded authorities, however, institutions may rebudget funds within the total costs awarded to cover salaries consistent with the institution's salary scale.

The total salary requested must be based on a full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

2. Research Development Support: Most awarding components at the NIH will provide up to \$20,000 per year is allowed for the following expenses: (a) tuition, fees, and books related to career development; (b) research expenses, such as supplies, equipment and technical personnel; (c) travel to research meetings or training; (d) statistical services including personnel and computer time. The amount of research development support is not uniform across all awarding components. Prospective candidates should contact the NIH component to which the application is targeted to ascertain the maximum amounts available.

The National Institute of Dental Research and the National Heart, Lung, and Blood INstitute will provide up to \$15,000 for research development support. The National Institute of Mental Health will provide up to \$50,000 for research development support.

3. Ancillary Personnel Support: Salary for mentors, secretarial and administrative assistance, etc., is not allowed.

4. Indirect costs: Indirect costs will be reimbursed at 8 percent of modified total direct costs, or at the actual indirect cost rate, whichever is less.

E. Evaluation: In carrying out its stewardship of human resource related programs, the NIH may begin requesting information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified, that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

F. Other Income: Fees resulting from clinical practice, professional consultation, or other comparable activities required by the research and research-related activities of this award may not be retained by the career award recipient. Such fees must be assigned to the grantee institution for disposition by any of the following methods:

The funds may be expended by the grantee institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefit payments must be within the established policies of the grantee institution.

The funds may be used for health-related research purposes.

The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks should be made payable to the Department of Health and Human Services, NIH and forwarded to the Director, Division of Financial Management, NIH, Bethesda, Maryland 20892. Checks must identify the relevant award account and reason for the payment.

Awardees may retain royalties and fees for activities such as scholarly writing, service on advisory groups, or honoraria from other institutions for lectures or seminars, provided these activities remain incidental and provided that the retention of such pay is consistent with the policies and practices of the grantee institution.

Usually, funds budgeted in an NIH supported research or research training grant for the salaries or fringe benefits of individuals, but freed as a result of a career award, may not be rebudgeted. The awarding component will give consideration to approval for the use of released funds only under unusual circumstances. Any proposed retention of funds released as a result of a career award must receive prior written approval of the NIH awarding component.

G. Special Leave: Leave to another institution, including a foreign laboratory, may be permitted if directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed 3 months. For longer periods, prior written approval of the NIH funding component is required. To obtain prior approval, the award recipient must submit a letter to the NIH describing the plan, countersigned by his or her department head and the appropriate institutional official. A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the career award will continue during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of the NIH funding component and will be granted only in unusual situations. Support from other sources is permissible during the period of leave. Such leave does not reduce the total number of months of program support for which an individual is eligible. Parental leave will be granted consistent with the policies of the NIH and the grantee institution.

H. Termination or Change of Institution: When a grantee institution plans to terminate an award, the NIH funding component must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination. If the individual is moving to another eligible institution, career award support may be continued provided:

A new career award application is submitted by the new institution;

The period of support requested is no more than the time remaining within the existing award period; and

The new application is submitted far enough in advance of the requested effective date to allow the necessary time for review.

The funding component may require a review by an initial review group and/or the appropriate National Advisory Council or Board. Alternatively, review may be carried out by staff within the NIH funding component depending upon the circumstances.

The Director of the NIH may discontinue an award upon determination that the purpose or terms of the award are not being fulfilled. In the event an award is terminated, the Director of the NIH shall notify the grantee institution and career award recipient in writing of this determination, the reasons therefor, the effective date, and the right to appeal the decision.

A final progress report, invention statement, and Financial Status Report are required upon either termination of an award or relinquishment of an award in a change of institution situation.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

This is a generic program announcement for the MCSDA. Therefore, all candidates are strongly encouraged to contact the staff person in the relevant institute or center listed under INQUIRIES. Such contact should occur early in the planning phase of application preparation. Such contact will help ensure that applications are responsive to the career development goals and policies of the individual institute or center.

Applications are to be submitted on form PHS 398 (rev. 9/91) and will be accepted on or before the receipt deadlines indicated in the application kit (February 1, June 1 and October 1). Forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, NIH, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/435-0714.

The application must address the following issues:

Candidate

- o Describe the candidate's commitment to a career in biomedical or behavioral research
- o Establish the candidate's potential to develop into an independent investigator.
- o Describe immediate and long-term career objectives, explaining how the award will contribute to their attainment.
- o Letters of recommendation. Three sealed letters of recommendation addressing the candidate's potential for a research career must be included as part of the application.

Career Development Plan

- o Describe the career development plan incorporating consideration of the candidate's goals and prior experience. It should describe a systematic plan to obtain the necessary basic biomedical or behavioral science background and research experience to launch an independent research career. More junior candidates with little previous research experience may require a phased developmental period in which the first year(s) of the award are largely of a didactic nature followed by a period of intense, supervised research experience. Candidates with more experience at the time of application may need a shorter developmental period and may already have an adequate basic science background. In any case, the career development plan must be tailored to the needs of the candidate and the ultimate goal of independence as a researcher.
- o Candidates seeking support from NIDR should also include a description of their plan to obtain the necessary clinical training
- o Candidates must describe plans to receive Instruction in the responsible conduct of research. These plans must detail the proposed subject matter, format, frequency, and duration of instruction. No award will be made if an application lacks this component.

Research Plan

- o Describe the research plan and the use of a basic or clinical science approach to a biomedical or behavioral problem. The research plan must be described as outlined in form PHS 398 including sections on the Specific Aims, Background and Significance, Progress Report/ Preliminary Studies, Research Design and Methods. The candidate should consult with the mentor regarding the development of this section.

Mentor's Statement

- o The application must include information on the mentor(s) including information on research qualifications and previous experience as a research supervisor. The applications must also include information to describe the nature and extent of supervision that will occur during the proposed award period.

Environment and Institutional Commitment

- o The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest including a high-quality research environment with staff capable of productive collaboration with the candidate. The sponsoring institution also must provide a statement of commitment to the candidate's development into a productive, independent investigator.

Budget

- o Budget requests must be provided according to the instructions in form PHS 398. The request for tuition and fees, books, travel, research development support, etc., must be justified and specified by category.

To identify the application as a response to this program announcement, check "YES" on item 2a of page 1 of the application and enter "PA-95-053, Mentored Clinical Scientist Development Award" and the name of the NIH institute or center that you would like your application to be assigned for funding.

Submit a signed, typewritten original of the application with Checklist, and five signed photocopies, in one package to:

Division of Research Grants
National Institutes of Health

6701 Rockledge Drive, Room 1040 MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

REVIEW CONSIDERATIONS

Applications will be reviewed for completeness by the Division of Research Grants and for responsiveness to this program announcement by the appropriate institute or center staff. Incomplete or nonresponsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the program announcement will be evaluated for scientific and technical merit by an appropriate peer review group convened in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

The following review criteria will be applied:

Candidate

- o Quality of the candidate's academic and clinical record,
- o Potential to develop as an independent researcher;
- o Commitment to a research career; and
- o Likelihood that the plan will contribute substantially to the achievement of scientific independence.

Career Development Plan

- o Likelihood that the career development plan will contribute substantially to the scientific development of the candidate;
- o Appropriateness of the content, the phasing, and the proposed duration of the career development plan for achieving scientific independence;

- o Consistency of the career development plan with the candidate's career goals; and
- o Quality of the proposed training in responsible conduct of research.

Research Plan

Reviewers recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator. Although it is understood that K08 applications do not require the level of detail necessary in regular research grant proposals, a fundamentally sound research plan must be provided. In general, less detail is expected with regard to research planned for the later years of the award, but the application should outline the general goals for these years.

- o Appropriateness of the research plan to the stage of research development and as a vehicle for developing the research skills as described in the career development plan;
- o Scientific and technical merit of the research question, design and methodology;
- o Relevance of the proposed research to the candidate's career objectives; and
- o Adequacy of the plan's attention to gender and minority issues.

Mentor

- o Appropriateness of mentor's research qualifications in the area of this application;
- o Quality and extent of mentor's proposed role in providing guidance and advice to the candidate;
- o Previous experience in fostering the development of researchers; and
- o History of research productivity and support.

Environment and Institutional Commitment

- o Applicant institution's commitment to the scientific development of the candidate and assurances that the institution intends the candidate to be an integral part of its research program;
- o Adequacy of research facilities and training opportunities;
- o Quality and relevance of the environment for scientific and professional development of the candidate; and
- o Applicant institution's commitment to an appropriate balance of research and clinical responsibilities.

Budget

- o Justification of the requested budget in relation to career development goals and research aims.

AWARD CRITERIA

The institute or center will notify the applicant of the board or council's action shortly after its meeting. Funding decisions will be made based on the recommendations of the initial review group and council/board, the need for research personnel in specific program areas, and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this program announcement are strongly encouraged especially during the planning phase of the application. Below is a listing of each institute's or center's program or grants management contacts.

Dr. Robin A. Barr
Office of Extramural Affairs
National Institute on Aging
7201 Wisconsin Avenue, Room 2C218, MSC 9205
Bethesda, MD 20892-9205
Telephone: (301) 496-9322
FAX: (301) 402-9245

Email: Barr@nihniagw.bitnet

Dr. Ernestine D. Vanderveen, Ph.D.

Division of Basic Research

National Institute on Alcohol Abuse and Alcoholism

6000 Executive Boulevard, Suite 402 MSC 7003

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Email: tvanderv@willco.niaaa.nih.gov

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Email: fcotter@willco.niaaa.nih.gov

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Email: m.dufour@willco.niaaa.nih.gov

Dr. Milton Hernandez

Office of Scientific Training and Manpower Development

National Institute of Allergy and Infectious Diseases

Solar Building, Room 3C21

Bethesda, MD 20892

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Extramural Programs
National Institute on Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-49E MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-5128
FAX: (301) 480-4543
Email: rl28b@nih.gov

Dr. John Schneider or Dr. Andrew Vargosko
Division of Cancer Biology, Diagnosis, and Centers
National Cancer Institute
Executive Plaza North, Room 520
Bethesda, MD 20892
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FAX: (301) 402-4472
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Institute of Diabetes and Digestive and Kidney Diseases 45 Center
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AUTHORITY AND REGULATIONS

The Mentored Clinical Scientist Development Awards are made under the authority of Title III, Section 301 of the Public Health Service (PHS) Act as amended (Public Law 78-410, as amended, 42 USC 241). The Code of Federal Regulations, Title 42 Part 52, and Title 45 part 74, are applicable to this program. This program is described in the Catalog of Federal Domestic Assistance No. 93.121. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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